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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

IN RE LIPOCINE INC. SECURITIES LITIGATION This Document Relates To: All Actions	Case No. 2:17CV00182 DB **DEFENDANTS' MOTION TO DISMISS AND MEMORANDUM IN SUPPORT** Judge Dee Benson

Pursuant to Rule 12(b)6 of the Federal Rules of Civil Procedure, Defendants Mahesh Patel and Morgan Brown ("Individual Defendants") and Defendant Lipocine, Inc. ("Lipocine" or "Company") (collectively, "Defendants"), by and through their attorneys, hereby submit this *Motion to Dismiss and Memorandum in Support* seeking to dismiss the Amended Complaint with prejudice. This motion is supported by the Declaration of Joni S. Jacobsen, filed concurrently herewith.

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INTRODUCTION

Lipocine Investor Group ("Plaintiff") made an investment in Lipocine Inc. ("Lipocine" or the "Company"), a biopharmaceutical company, hoping the FDA would approve the Company's new drug candidate. The FDA, however, identified deficiencies related to the dosing algorithm for the label. Thus, the FDA concluded that it could not approve the Company's new drug application ("NDA") with the dosing (*i.e.*, titration) scheme as submitted because differences in the dosing schemes used in the Phase 3 clinical trial and the NDA led to discordance in titration decisions which the FDA found unacceptable. As a result, additional clinical testing is required. Unhappy that the FDA did not immediately approve the drug and unwilling to wait for additional testing, which is currently ongoing, Plaintiff seeks to recover its losses through this litigation. But Plaintiff cannot recover in securities fraud simply because it made an unsuccessful investment. To allow otherwise would turn securities actions into insurance policies, permitting plaintiffs to recoup investments whenever they did not pan out as hoped.

To state a cause of action for securities fraud, it is not enough for Plaintiff to merely allege that Defendants knew about the differences in the Phase 3 trial and NDA dosing schemes. Instead, Plaintiff must plead *particularized facts* showing that Defendants knew or should have known that the NDA was unlikely to be approved because of the differences in the dosing schemes and *intentionally* misled investors by omitting that fact from its disclosures. Plaintiff's allegations do not come close to meeting this heightened standard. While Plaintiff attempts to infer an intent to defraud from the Individual Defendants' mere positions at the Company, their signing of SEC filings, and confidential witnesses' vague assertions that the Individual Defendants met with their

subordinates and were involved "in one way or another" with the drug, courts routinely hold that such generalized allegations do not suffice.

Plaintiff's allegations also simply make no sense. Plaintiff fails to explain why the Company would work with the FDA in designing clinical testing protocols, invest vast sums of money into Phase 3 testing, and then continue to finance the cost of additional Phase 3 testing, if all the while Defendants knew the dosing scheme submitted in the NDA was unacceptable and unlikely to receive FDA approval. Far from the cynical picture painted by Plaintiff, what happened here is *exactly* what Lipocine repeatedly warned its investors could happen: after scrutinizing the NDA, the FDA informed the Company that it had identified deficiencies in the label language, and thus, could not approve the NDA in its present form and requested additional clinical testing. Because Plaintiff has not pleaded particularized facts demonstrating an intent to defraud, relying instead on fraud-by-hindsight, and because any inference of fraudulent intent is not as compelling as the inference of nonculpable intent, Plaintiff's Amended Complaint should be dismissed for this reason alone.

Plaintiff's pleading deficiencies do not stop there. Plaintiff also fails to allege Defendants made any material misstatement or omissions. The securities laws do not compel companies to disclose information simply because an investor would like to know it. Here, the Company had no duty to disclose facts about dosing schemes and the confidential details regarding its NDA submission. Its silence on these matters thus is not actionable. Further, Plaintiff does not identify which of the many pages of disclosures it quotes verbatim were actually misleading, and thus has not pleaded an actionable misstatement with particularity. For these reasons and those set forth below, Defendants request that this Court dismiss the Amended Complaint with prejudice.

BACKGROUND

Lipocine is a biopharmaceutical company that focuses on developing oral drug delivery technology. Am. Compl. ¶ 15. Its leading drug candidate is LPCN 1021, an oral testosterone replacement drug. Am. Compl. ¶ 2. Although the Company had two other drugs in its portfolio during the Class Period, both of those drug candidates lagged behind LPCN 1021 in the FDA regulatory approval process. Am. Compl. ¶ 16. As disclosed to its investors, Lipocine has not yet received FDA approval for any of its drug candidates, and it did not expect to generate any revenue "unless and until [it] obtain[s] regulatory approval of LPCN 1021 or other products." Am. Compl. ¶ 18.

The gravamen of Plaintiff's Complaint is whether "the Company failed to disclose that the reported results from the Phase 3 clinical trial . . . related to a titration scheme that differed significantly from the proposed titration scheme for clinical practice thus creating a substantial risk that the FDA would reject the LPCN 1021 NDA." Am. Compl. ¶ 21. Dose titration is the process of adjusting a patient's dosage until optimal results are reached. Am. Compl. ¶ 16. The Company never touted or even disclosed the dose titration scheme used in the Phase 3 clinical trial for LPCN 1021, nor the dose titration scheme proposed in the NDA. Nor did it make any comments regarding the likelihood of FDA approval—instead carefully warning investors of the risks associated with the approval process. *See infra* notes 3-10 and accompanying text. However, after the FDA unexpectedly determined that it could not approve the NDA in its current form, the Company properly disclosed that the FDA reached this determination because it identified deficiencies relating to the dosing algorithm for the label; namely, the FDA determined the differences in the titration schemes for the Phase 3 trial and NDA "le[d] to discordance in titration

decisions between the Phase 3 trial and real-world clinical practice." Am. Compl. ¶ 38. Shortly after this disclosure, Plaintiff filed suit.

Obtaining FDA approval of a potential drug candidate is a time-consuming, costly, and rigorous process that requires continual cooperation with the FDA. *See* Ex. A,[1] Lipocine 3/11/2015 Form 10-K at 11-13, 22-23.[2] Prior to approval, the FDA requires drug candidates to undergo clinical testing that is subject to strict FDA requirements. *Id*. at 12. There are typically three phases of clinical trials. *Id*.; Am. Compl. ¶ 15. Phase 1 clinical trials usually take one or two years to complete, involve only a small number of healthy human subjects, and the primary purpose of this trial is to, among other things, evaluate "the drug's activity, schedule and dose." *See* Ex. A, Lipocine 3/11/2015 Form 10-K at 12. Phase 2 trials can take one to three years to complete, involve a small to moderate number of patients, and is designed to, among other things, preliminarily evaluate efficacy, adverse effects, safety risks, and optimal dose. *Id*. Phase 3 clinical trials take approximately two to five years to complete, involve testing on several hundred to several thousand patients, and is designed to, among other things, "further evaluate dosage, [and] clinical efficacy and safety." *Id*.; Am. Compl. ¶ 15. According to the Company's disclosures, the FDA generally requires two adequate Phase 3 clinical trials prior to approval of an NDA. *See* Ex. A, Lipocine 3/11/2015 Form 10-K at 12. Progress reports detailing the results of clinical trials

[1] All exhibits cited herein refer to the exhibits attached to the Declaration of Joni S. Jacobsen, which was filed concurrently with this Motion and Memorandum.

[2] Defendants ask this Court to take judicial notice of Exhibits A-G. *See In re Zagg Sec. Litig*, No. 2:12-CV-852, 2014 WL 505152, *1 (D. Utah Feb. 7, 2014) (J., Benson); *see also Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA–04CV–1030–RPM, 2005 WL 4161977, *2 (D. Colo Oct. 20, 2005).

must be submitted at least annually to the FDA, and the FDA may suspend a clinical trial at any time on various grounds. *Id*. at 13.

Upon completion of Phase 3 testing, a sponsor assembles data from all clinical trials, preclinical studies, and product development, along with descriptions of the manufacturing process, proposed labeling, and other information, and submits it to the FDA in an NDA. *Id*.; Am. Compl. ¶ 14. The FDA's review of the NDA can take up to one year to complete. *See* Ex. A, Lipocine 3/11/2015 Form 10-K at 13. In light of these demanding, time-consuming, and costly requirements, the system of obtaining new drug approval in the United States is "generally considered to be the most rigorous in the world." *See id*. at 11.

Before the class period began and throughout the entire class period, the Company repeatedly warned investors that the FDA may not approve the NDA for LPCN 1021 or may require additional testing. For example, the Company stated that "The FDA may refuse to approve an NDA . . . or may require additional clinical data,"[3] that "we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or even terminate further development,"[4] that the Company "cannot ensure successful product development or that we will obtain regulatory approval or successfully commercialize any of our product candidates,"[5] and that

[3] Ex. A, Lipocine 3/11/2015 Form 10-K at 13; Ex. B, Lipocine 3/10/2016 Form 10-K at 14. *See also* Ex. C, Lipocine 11/12/2015 Form 10-Q at 25 ("LPCN 1021 . . . is under regulatory review and may not receive regulatory approval or be successfully commercialized."); Ex. D, Lipocine 8/11/2015 Form 10-Q at 25 ("LPCN 1021 . . . is still under clinical development and may not receive regulatory approval or be successfully commercialized.").

[4] Ex. A, Lipocine 3/11/2015 Form 10-K at 16; Ex. B, Lipocine 3/10/2016 Form 10-K at 17; Ex. C, Lipocine 11/12/2015 Form 10-Q at 25; Ex. D, Lipocine 8/11/2015 Form 10-Q at 25.

[5] Ex. A, Lipocine 3/11/2015 Form 10-K at 22; Ex. B, Lipocine 3/10/2016 Form 10-K at 25. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 20 ("[W]e may never succeed in obtaining regulatory

the "FDA may also require that we . . . run additional trials."[6] Additionally, because the Company had never before submitted an NDA for any drug candidate, the Company warned investors that "[w]e have never marketed or commercialized a drug product," and as a result, "any predictions about our future performance may not be as accurate as they could be if were further along our commercialization path." *See* Ex. A, Lipocine 3/11/2015 Form 10-K at 22; Ex. B, Lipocine 3/10/2016 Form 10-K at 24.

The Company also cautioned that its expectations regarding the success of its drug candidates "may not be realized for many scientific, business or other reasons," and that the Company thus could not "assure investors" that it could adhere to any specified schedule.[7] It then specifically warned that the "actual timing" of "regulatory approval" can "vary dramatically" from its goals for many reasons, including "requirements for additional clinical trials and uncertainties inherent in the regulatory approval process and regulatory submissions."[8] It further warned that

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approval or commercializing any of these product candidates."); Ex. C, Lipocine 11/12/2015 Form 10-Q at 19 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 19 (same).

[6] Ex. A, Lipocine 3/11/2015 Form 10-K at 23; Ex. B, Lipocine 3/10/2016 Form 10-K at 26. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 20 ("[T]he FDA may require additional clinical trials or non-clinical studies."); Ex. C, Lipocine 11/12/2015 Form 10-Q at 19 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 20 (same).

[7] *See* Ex. A, Lipocine 3/11/2015 Form 10-K at 16; Ex. B, Lipocine 3/10/2016 Form 10-K at 17. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 20-21 ("The cost of clinical trials may vary significantly over the life of a project as a result of uncertainties in clinical development, including, among others . . . the cost, timing and outcome of regulatory review" and "[c]linical development timelines, the probability of success and development costs can differ materially from expectations and results from our clinical trials may not be favorable"); Ex. C, Lipocine 11/12/2015 Form 10-Q at 19-20 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 20 (same).

[8] Ex. A, Lipocine 3/11/2015 Form 10-K at 16; Ex. B, Lipocine 3/10/2016 Form 10-K at 17. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 26 ("Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any

the FDA may "delay, limit or deny approval for many reasons," including the possibility that "the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials," that "the FDA may disagree with our interpretation of data from our . . . clinical trials or may require that we conduct additional trials," and that the FDA's review of the NDA may result in the request for "additional . . . clinical trials."[9] Finally, the Company cautioned that "clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products."[10]

On June 29, 2016, the Company issued a press release disclosing that it received a complete response letter ("CRL") from the FDA, informing the Company that the FDA had "identified deficiencies related to the dosing algorithm for the label," and that the NDA "cannot be approved in its present form" because "the proposed titration scheme for clinical practice was significantly different from the titration scheme used in the Phase 3 trial leading to discordance in titration decisions between the Phase 3 trial and real-world clinical practice." Am. Compl. ¶ 38. Shortly

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future losses or when we will become profitable, if at all."); Ex. C, Lipocine 11/12/2015 Form 10-Q at 28 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 27 (same).

[9] Ex. A, Lipocine 3/11/2015 Form 10-K at 23; Ex. B, Lipocine 3/10/2016 Form 10-K at 25. *See also* Ex. C, Lipocine 11/12/2015 Form 10-Q at 25 ("[T]he FDA may . . . require us to perform additional clinical trials or studies or provide additional information in order to secure approval.")

[10] Ex. A, Lipocine 3/11/2015 Form 10-K at 23; Ex. B, Lipocine 3/10/2016 Form 10-K at 26. *See also* Ex. D, Lipocine 8/11/2015 Form 10-Q at 25 ("A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving positive results in early stage development.").

thereafter, Plaintiff filed suit alleging Defendants violated §§ 10(b) and 20(a) of the Securities and Exchange Act.

ARGUMENT

To state a cause of action under § 10(b), Plaintiff must allege (1) a misleading statement or omission of material fact, (2) made in connection with the purchase or sale of securities, (3) with scienter, *i.e.*, an intent to defraud or deliberate recklessness, (4) reliance, and (5) damages. *City of Philadelphia v. Fleming Cos., Inc.* ("*Fleming*"), 264 F.3d 1245, 1257-58 (10th Cir. 2001). For the reasons set forth below, Plaintiff has failed to plead a strong inference or scienter, or a misleading statement or omission of material fact, both of which are subject to heightened pleading standards.

I. PLAINTIFF HAS A HEAVY PLEADING BURDEN

As an initial matter, when deciding a motion to dismiss under Rule 12(b)(6), the Court must presume the truth of well-pleaded facts. *In re Zagg Sec. Litig*, ("*Zagg*") No. 2:12-CV-852, 2014 WL 505152, *3 (D. Utah Feb. 7, 2014) (J., Benson). Importantly, however, the Court need not accept conclusory allegations as true. *Id*. Nor should it accept as true deductions and opinions that are "couched as facts." *Id*. Further, while the Court must draw all reasonable inferences in favor of Plaintiff, the Amended Complaint can only survive if it "contains 'enough facts to state a claim to relief that is plausible on its face.'" *Id*. (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

However, to adequately allege a securities violation, Plaintiff must also satisfy the "more rigorous pleading requirements" of Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *Caprin v. Simon Transp. Servs.*, 112 F. Supp. 2d 1251, 1255 (D. Utah 2000); *see also Fleming*, 264 F.3d at 1258. Rule 9(b) requires plaintiffs to plead particularized facts in support of

any claim alleging fraud, including security fraud. *Caprin*, 112 F. Supp. 2d at 1255; *In re Imergent Sec. Litig.*, ("Imergent") No. 2:05–CV–204, 2009 WL 3731965, *5 (D. Utah Nov. 2, 2009) (J., Benson) ("[A]verments of fraud . . . shall be stated with particularity."). Under the PSLRA, plaintiffs must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." *Imergent*, 2009 WL 3731965 at *5. Additionally, when pleading scienter—the third element of a securities fraud claim—plaintiffs must "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *Id*. (emphasis added). These rules were designed to "discourage spurious securities lawsuits" and eliminate abusive litigation filed in response to any "significant change in an issuer's stock price." *Fleming*, 264 F.3d 1258-59; *see also Caprin*, 112 F. Supp. 2d at 1255 (PSLRA further heightened pleading standards because "the previously existing standards had not prevented abuse of the securities laws by private litigants").

For the reasons set forth below, Plaintiff has not met its heavy pleading burden, and the case should be dismissed with prejudice.

II. PLAINTIFF HAS NOT PLEADED A STRONG INFERENCE OF SCIENTER

Plaintiff must—but fails—to plead particularized facts demonstrating a strong inference that Defendants acted with scienter, *i.e.*, an intent to defraud. *Fleming*, 264 F.3d at 1261. The term scienter connotes "a mental state embracing intent to deceive, manipulate, or defraud." *Zagg*, 2014 WL 505152, *5. Section 10(b) claims do not reach unintentional conduct. *Caprin*, 112 F. Supp. 2d at 1258. Rather, to adequately plead scienter, plaintiffs must allege particularized facts

showing that Defendants *knew* of the allegedly omitted fact, and *also knew* that failing to disclose this fact would likely mislead investors. *Fleming*, 264 F.3d at 1261. Although the knowledge requirement in this context may be satisfied under a deliberate recklessness standard, courts are "cautious" to impose liability based on reckless conduct and only do so if the defendant's knowledge of a fact "was so obviously material that the defendant must have been aware both of its materiality *and* that its non-disclosure would likely mislead investors." *Id*. (emphasis added); *Zagg*, 2014 WL 505152, *5. Where the plaintiff merely alleges that defendants had knowledge of facts that turn out be material, it has not demonstrated "that the defendant intentionally withheld those facts from, or recklessly disregarded the importance of those facts to, a company's shareholders in order to deceive, manipulate, or defraud." *Fleming*, 264 F.3d at 1260.

Further, when deciding whether the pleading requirement for scienter has been met, courts must consider both plaintiff's allegations of scienter and the "plausible nonculpable explanations for the defendant's conduct." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). To survive a motion to dismiss, the plaintiff's preferred inference of fraudulent intent must be "cogent and at least as compelling as any opposing inference." *Zagg*, 2014 WL 505152 at *4. Inferences of scienter that are merely reasonable or permissible will not do. *Id*. at *4.

Accordingly, here, it is not enough for Plaintiff to allege merely that Defendants knew (or deliberately disregarded) that the titration scheme proposed in the NDA was different from the titration scheme used during Phase 3. Instead, in order to plead a strong inference of scienter, Plaintiff must allege particularized facts demonstrating that Defendants knew that the differences in the dosing schemes created a "substantial risk" that the FDA would not approve the NDA in its current form, and Defendants *intentionally* withheld this information in order to mislead investors.

See Fleming, 264 F.3d at 1261. Plaintiff has not come close to meeting its burden—Plaintiff fails to allege particularized facts, and Plaintiff's theory of liability makes no sense. Rather than articulating facts demonstrating fraudulent intent, Plaintiff relies on impermissible fraud by hindsight: Defendants must have known that the FDA would deny the NDA because that is ultimately what came to pass. This is exactly what the demanding pleading standards of the PSLRA were designed to prevent. *See id*. at 1260.

A. Plaintiff Has Not Alleged Particularized Facts From Which This Court Can Infer a Strong Inference of Scienter.

Plaintiff attempts to infer scienter from the Individual Defendants' mere positions at the Company, the fact that the Individual Defendants signed SEC filings, and from vague allegations attributed to confidential witnesses. These generalized allegations do not suffice under the PSLRA's heightened pleading standards.

First, Plaintiff contends that "[b]y virtue of their positions at Lipocine," Defendants either knew or must have known of the differences in the titration schemes and that the differences in the titration schemes put the NDA approval at "substantial risk." Am. Compl. ¶ 21, 40. This is insufficient. Courts routinely hold that no inference of scienter can be drawn from defendants' mere positions.

The Tenth Circuit's seminal decision in *Fleming* is instructive. In that case, plaintiffs alleged that the defendants omitted material information about a pending lawsuit from its public disclosures. *Fleming*, 264 F.3d at 1249. Plaintiffs argued that knowledge of this pending lawsuit could be inferred from defendants' senior positions at the company. The Tenth Circuit disagreed. It held that plaintiffs' generalized allegations were "exactly the type of conclusory assertions of liability that the PSLRA was designed to prevent." *Id*. at 1264. It explained that "[g]eneralized

imputations of knowledge do not suffice, regardless of defendants' positions within the company," and therefore, "allegations that a securities fraud defendant, because of his position within the company, 'must have known' a statement was false or misleading are 'precisely the types of inferences which [courts], on numerous occasions, have determined to be inadequate to withstand Rule 9(b) scrutiny." *Id.* at 1264 (quoting *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 539 (3d Cir. 1999)) (alterations in original). And even if plaintiffs had sufficiently pleaded knowledge of the pending lawsuit—which the court emphasized they did not—the Court further held that the issue was *not* simply "whether Defendants knew the underlying facts, but whether Defendants knew that not disclosing the [] Litigation posed substantial likelihood of misleading a reasonable investor." *Id.* at 1264. No such inference could be made from mere positions. *Id.*

So too here. The Tenth's Circuit's opinion in *Fleming* is binding upon this Court, and as such, no inference of scienter can be gleaned from the Individual Defendants' mere positions.

Second, to the extent Plaintiff contends that a strong inference of scienter can be inferred from the mere fact that the Individual Defendants signed the Company's SEC filings, this argument must be rejected. Numerous courts, including the Tenth Circuit, have held that such generalized allegations of scienter will not suffice. For example, in *Fleming*, the individual defendants signed the allegedly fraudulent public filing, yet the Tenth Circuit nevertheless did not infer a strong inference of scienter. *Fleming*, 264 F.3d at 1250. The Tenth Circuit reached the exact same result in *Zagg*, holding that mere fact of nondisclosure, "without some other facts evidencing [that the defendants] signed the filings with the knowledge that they omitted a required disclosure," is insufficient. *In re Zagg, Inc. Sec. Litig.* ("*Zagg*"), 797 F.3d 1194, 1204 (10th Cir. 2015) (affirming Judge Benson's opinion); *see also Anderson v. First Sec. Corp.*, 249 F. Supp. 2d 1256, 1270 (D.

Utah 2002) (rejecting plaintiff's attempt to infer scienter from defendants' positions and the fact that they were responsible for the company's public filings). The same result is compelled here. This Court cannot infer a strong inference of scienter from the mere fact that the Individual Defendants signed SEC filings.

Third, Plaintiff cannot avoid dismissal by simply attributing generalized allegations of fraud to confidential witnesses. Indeed, Plaintiff's two CWs merely assert that the Individual Defendants had meetings with their subordinates and were involved "in one way or another" with LPCN 1021. Generalized allegations—regardless of their source—are insufficient. *Fleming*, 264 F.3d at 1263 ("We decide cases on facts, not labels."). As such, it is the *substance* of allegations that matters, and generalized allegations are not rendered sufficiently particular merely because a confidential witness is alleged to be the source. *See Anderson v. First Sec. Corp.*, 249 F. Supp. 2d 1256, 1265-66 (D. Utah 2002) ("[W]hen a plaintiff relies on a confidential source, the weight given to that information is based solely on the facts alleged and not the source itself. Where the information is deficient in particularity, it does not add anything that the information comes from another source."). Furthermore, courts in the Tenth Circuit apply a "steep discount" to allegations attributed to unnamed sources because they "may have axes to grind[,] could be lying[,] or maybe doesn't even exist." *In re FX Energy, Inc. Sec. Litig.* ("*FX Energy*"), Nos. 2:07–CV–874, 2:07–CV–938, 2:07–CV–966, 2009 WL 1812828, *10 (D. Utah June 25, 2009) (internal quotations removed) (citing *Higginbotham v. Baxter Int'l Inc.*, 495 F.3d 753, 757 (7th Cir. 2007)).

The opinion in *FX Energy* is instructive. In that case, plaintiffs accused defendants of implying in its public disclosures that two wells had a greater chance of being more successful than the company's other wells, when in fact those two wells turned out to be dry. *FX Energy*,

2009 WL 1812828, at *9. In an attempt to infer scienter, plaintiffs alleged that a confidential witness warned defendants that the two wells were "bad prospects." *Id*. at 10. The court found this allegation insufficient. After noting that it is proper to apply a "steep discount" to allegations attributed to unnamed sources, it held that the generalized allegation attributed to the confidential witness was not compelling because it did not specify to whom the witness made this statement, when the conversation occurred, or what was said in response. *Id*. at 10. Further, although the allegations described the confidential witness' own opinion about the wells' prospects, it appears that defendants simply disagreed with her opinion—a result that is not indicative of fraud. *Id*.

As in *FX Energy*, Plaintiff's allegations attributed to two confidential witnesses are not particularized and must be rejected. According to the Amended Complaint, CW1 believes that "everyone" was "involved" with LPCN 1021 "in one way or another." Am. Compl. ¶ 18. But, as noted above, it is not enough to allege that Defendants "must have known" of an omitted fact. *Fleming*, 264 F.3d at 1264. Rather, Plaintiff must demonstrate that Defendants intentionally omitted this fact from its disclosures in order to mislead investors. *Id*. at 1261. Here, the vague allegation attributed to CW1 does not come close to establishing that Defendants knew (or deliberately disregarded) that failure to disclose the titration schemes would mislead investors. Indeed, the CW allegations in this case are thus even *weaker* than those in *FX Energy*; the CW here does not even allege that she warned Defendants about the risks associated with varying titration schemes.

Similarly, no inferences of knowledge can be drawn from the vague assertion that CW1's boss and other vice presidents "reported regularly" to the Individual Defendants, and that CW1's boss met with Defendant Patel "regulatory [sic] about Company business." Am. Compl. ¶ 18.

Plaintiff does not allege how often those meetings occurred, when those meetings occurred, who was present, or—most importantly—what was even discussed. As in *FX Energy*, no inference of knowledge can be drawn from the unremarkable allegation that the Individual Defendants met with their subordinates. Likewise, CW1's belief that the Individual Defendants "certainly monitored" the Phase 3 "results," Am. Compl. ¶18, and CW2's opinion that the Individual Defendants were "'very involved' in the Phase 3 trial conduct and results," Am. Compl. ¶ 19, are vague at best. As above, neither of these allegations demonstrates that Defendants knew that the differences in the titration schemes would cause the FDA to not approve the NDA or that Defendants intentionally withheld information in order to mislead investors. *Fleming*, 264 F.3d at 1261. Nor must this Court accept Plaintiff's contention that Defendants "must have known" that the FDA would not approve the NDA since that is ultimately what came to pass, as courts routinely reject attempts to plead a securities violation based on nothing more than fraud-by-hindsight. *See id.* (explaining why the Tenth Circuit's rejects "the 'fraud by hindsight' method of pleading in securities fraud cases").

For these reasons—and especially given this Court's mandate to apply a "steep discount" to allegations attributed to unidentified witnesses, *FX Energy*, 2009 WL 1812828 at *10—no inference of scienter can be drawn from vague allegations attributed to Plaintiff's confidential witnesses, nor from mere allegations regarding Defendants' positions or SEC filings.

B. Any Inference of Scienter Must Be Discounted, And Is Not As Compelling As Plausible, Nonculpable Explanations for the Defendants' Conduct.

As noted by the Supreme Court, it is not enough to allege a reasonable or permissible inference of scienter. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). To the contrary, Plaintiff must allege a strong inference of scienter that is cogent and *at least as*

compelling as any plausible, nonculpable inference. *Id*. This is an "inherently comparative" inquiry and requires the Court to weigh the competing inferences. *In re Zagg, Inc. Sec. Litig.*, 797 F.3d 1194, 1202 (10th Cir. 2015). Here, any inference of scienter is undermined by the absence of any cognizable motive to commit fraud and Defendants' robust disclosures warning of the risks inherent in the FDA approval process. Moreover, Plaintiff's inference of scienter is not cogent or as compelling as any opposing inference. The Amended Complaint should be dismissed.

As an initial matter, even if *some* inference of scienter could be drawn from the allegations in the Amended Complaint—which it cannot—any inference of scienter would be undercut by the fact that Plaintiff has not alleged *any* motive for the alleged fraud. For example, Plaintiff does not allege that the Individual Defendants sold stock at an inflated price, or that they personally benefitted in some other manner from making the alleged misrepresentations. *See Fleming*, 264 F.3d at 1270 (no motive alleged where plaintiff failed to plead stock sales or other concrete and personal benefit). Likewise, Plaintiff fails to explain why Defendants would, on the one hand, work with the FDA when designing Phase 3 protocols,[11] spend vast sums of money to complete Phase 3 testing,[12] and then continue to invest large sums of money in the new Phase 3 studies that

[11] *See* Ex. F, 12/5/2012 Lipocine Press Release (announcing it "recently met with FDA and received guidance and go ahead for the Company's pivotal Phase III study for . . . LPCN 1021," noting FDA's feedback into "the design of our Phase III protocol.").

[12] *See e.g.*, Ex. A, 3/11/2015 Lipocine Form 10-K at 45 (disclosing anticipated LPCN 1021 research and development costs of "$2 to $3 million per quarter," $8 million to complete process, noting that "the FDA may require additional clinical trials or non-clinical studies," the cost of which could "vary significantly").

are currently ongoing,[13] while, on the other hand, knowingly defraud investors by hiding the fact that its NDA submission was likely to fail and new Phase 3 protocols would be required. Where, as here, Plaintiff makes no attempt to explain why the Defendants would engage in the alleged fraud, it cuts against an inference of scienter. *In re Level 3 Comm'ns, Inc. Sec. Litig.*, 667 F.3d 1331, 1347 (10th Cir. 2012) ("The absence of a motive allegation . . . is not dipositive," but is "relevant" and "counts against scienter.") (*citing Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 325 (2007)); *Anderson v. Spirit AeroSystems Holdings, Inc.*, 105 F. Supp. 3d 1246, 1267 (D. Kan. 2015) (*aff'd* 827 F.3d 1229 (10th Cir. 2016)) (lack of motive undermines inference of scienter where "it [was] not clear" what defendants "had to gain" by engaging in alleged fraud).

Likewise, the Company's disclosures further undercut any inference of scienter. Throughout the class period (and even before the class began), the Company repeatedly warned that the FDA would subject its drug to rigorous standards and may require additional testing or refuse approval altogether. For example, the Company warned, among other things, that:

- "The FDA may refuse to approve an NDA . . . or may require additional clinical data,"[14]
- "[The Company] may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or even terminate further development,"[15]

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[13] *See id.*; *see also* Ex. G, 3/6/2017 Lipocine Form 10-K at 55 (LPCN 1021 research and development costs were nearly $3.5 million in 2016, and Company expects such costs to increase with additional Phase 3 studies requested by the FDA).

[14] Ex. A, Lipocine 3/11/2015 Form 10-K at 13; Ex. B, Lipocine 3/10/2016 Form 10-K at 14. *See also* Ex. C, Lipocine 11/12/2015 Form 10-Q at 25 ("LPCN 1021 . . . is under regulatory review and may not receive regulatory approval or be successfully commercialized."); Ex. D, Lipocine 8/11/2015 Form 10-Q at 25 ("LPCN 1021 . . . is still under clinical development and may not receive regulatory approval or be successfully commercialized.").

[15] Ex. A, Lipocine 3/11/2015 Form 10-K at 16; Ex. B, Lipocine 3/10/2016 Form 10-K at 17; Ex. C, Lipocine 11/12/2015 Form 10-Q at 25; Ex. D, Lipocine 8/11/2015 Form 10-Q at 25.

- The Company "cannot ensure successful product development or that we will obtain regulatory approval or successfully commercialize any of our product candidates,"[16] and
- The "FDA may also require that we . . . run additional trials."[17]

The Company further cautioned that it had never before submitted an NDA,[18] and the "actual timing" of "regulatory approval" can "vary dramatically" from the Company's goals for many reasons, including "requirements for additional clinical trials and uncertainties inherent in the regulatory approval process and regulatory submissions."[19] Further, the Company explicitly stated that "[g]enerally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA," which is *exactly* what ultimately occurred here. *See* Ex. A, Lipocine 3/11/2015 Form 10-K at 12; *see also supra* notes 3-10 and accompanying text (listing additional warnings). These disclosures undercut any inference of scienter because they rebut any argument

[16] Ex. A, Lipocine 3/11/2015 Form 10-K at 22; Ex. B, Lipocine 3/10/2016 Form 10-K at 25. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 20 ("[W]e may never succeed in obtaining regulatory approval or commercializing any of these product candidates."); Ex. C, Lipocine 11/12/2015 Form 10-Q at 19 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 19 (same).

[17] Ex. A, Lipocine 3/11/2015 Form 10-K at 23; Ex. B, Lipocine 3/10/2016 Form 10-K at 26. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 20 ("[T]he FDA may require additional clinical trials or non-clinical studies."); Ex. C, Lipocine 11/12/2015 Form 10-Q at 19 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 20 (same).

[18] Ex. A, Lipocine 3/11/2015 Form 10-K at 16; Ex. B, Lipocine 3/10/2016 Form 10-K at 17.

[19] Ex. A, Lipocine 3/11/2015 Form 10-K at 16; Ex. B, Lipocine 3/10/2016 Form 10-K at 17. *See also* Ex. E, Lipocine 5/9/2016 Form 10-Q at 26 ("Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all."); Ex. C, Lipocine 11/12/2015 Form 10-Q at 28 (same); Ex. D, Lipocine 8/11/2015 Form 10-Q at 27 (same).

that "Defendants were attempting to hide information or mislead the public." *Anderson v. Spirit AeroSystems Holdings, Inc.*, 105 F. Supp. 3d 1246, 1266 (D. Kan. 2015).

Finally, as the Tenth Circuit recognized in *In re Zagg*, "[e]ven if we were to give the plaintiffs the benefit of saying that the complaint gives rise to some plausible inference of scienter, it is not the strong inference required by the PSLRA" because it was not "at least as strong" as the plausible, nonculpable inference. *In re Zagg, Inc. Sec. Litig.*, 797 F.3d 1194, 1207 (10th Cir. 2015) (affirming Judge Benson). The only plausible explanation for the events that transpired here is that, after subjecting LPCN 1021 to its strict standards, the FDA determined that more clinical testing was necessary and that the NDA could not be approved in its present form. Indeed, as noted above, this is *exactly* what the Company repeatedly warned could happen in its public disclosures.[20] While Plaintiff would apparently have this Court believe that the Defendants acted fraudulently simply for the sake of acting fraudulently, this is untenable. Nothing in the Amended Complaint supports such a cynical explanation of events. *See Karacand v. Edwards*, 53 F. Supp. 2d 1236, 1248 (D. Utah 1999) ("an unwarranted inference" that has no factual support is no more than a "conclusory allegation[] that cannot be credited"). Plaintiff's unsupported inference of scienter thus is neither cogent nor at least as compelling as the opposing inference. *See Anderson*,

[20] Both before and throughout the Class Period, the Company warned that "[m]arket prices for shares of biotechnology and biopharmaceutical companies such as ours are often volatile," and that the Company's stock price "may fluctuate significantly in response to a number of factors, most of which we cannot control, including: plans for, progress of and results from clinical trials of our product candidates; [and] the failure of the FDA to approve our product candidates." Ex. A, Lipocine 3/11/2015 Form 10-K at 31; *see also* Ex. B, Lipocine 3/10/2016 Form 10-K at 33-34 (same); Ex. E, Lipocine 5/9/2016 Form 10-Q at 12 (expected volatility in 2016 was 82.70%); Ex. C, Lipocine 11/12/2015 Form 10-Q at 11 (expected volatility in 2015 was 81.20%); Ex. D, Lipocine 8/11/2015 Form 10-Q at 11 (expected volatility in 2015 was 80.95%).

105 F. Supp. 3d 1269-70 (plaintiff's allegation that defendants, who had nothing to gain, intentionally engaged in fraudulent conduct was weaker than inference of non-fraudulent intent).

Accordingly, whether the allegations are viewed individually or holistically, Plaintiff fails to allege a strong inference of scienter and the Amended Complaint must therefore be dismissed. Indeed, courts in the Tenth Circuit have routinely rejected similar generalized allegations of scienter cobbled together in an attempt to meet this high bar. *See Fleming*, 264 F.3d at 1263-1270 (no inference of scienter from allegations of senior positions, large impact alleged fraud on company, generalized corporate motives, and conclusory assertions); *Imergent*, 2009 WL 3731965, at *7-11 (J. Benson) (*aff'd sub nom. Dronsejko v. Thorton*, 632 F. 3d 658 (10th Cir. 2011)) (no inference of scienter from accounting violations, magnitude of the fraud, and auditing "red flags"); *Zagg*, 2014 WL 505152 at *5-7 (J., Benson) (*aff'd* 797 F.3d 1194 (10th Cir. 2015)) (no inference of scienter from defendants' positions and purported failure to disclose facts).[21]

III. PLAINTIFF HAS NOT ALLEGED AN ACTIONABLE MISSTATEMENT

Plaintiff complains that the Defendants "failed to disclose" that Phase 3 results were achieved using a different titration scheme than the one proposed in the NDA, and that the differences in the titration schemes created a substantial risk that the FDA would deny the NDA. Am. Compl. ¶ 21. But Plaintiff fails to allege or even explain how this so called "omission" rendered any of Defendants' statements false or misleading. In fact, Plaintiff identifies *no statement* where the Company opined on the likelihood of NDA approval based on Phase 3 results,

[21] *See also Noble Asset Mgmt v. Allos Therapeutics, Inc.*, No. CIVA–04CV–1030–RPM, 2005 WL 4161977, *13 (D. Colo Oct. 20, 2005) (holding that plaintiff's vague allegations attributed to a confidential witness were insufficient and noting that when the confidential witness is unnamed, allegations musts be "particularly detailed, numerous, plausible, or objectively verifiable").

or in any way touted or even referenced the titration schemes. Plaintiff fails to allege Defendants had any duty to disclose the allegedly omitted information, and fails to identify any alleged misstatement. Plaintiff's Amended Complaint should be dismissed.

A. Silence, Absent a Duty to Disclose, Is Not Actionable.

Silence is not misleading—and thus is not actionable—absent a duty to disclose. *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1125 (10th Cir. 1997) (citing *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1998)). A duty to disclose does not exist simply because a particular fact is material or would be of interest to an investor. *Karacand v. Edwards*, 53 F. Supp. 2d 1236, 1243 (D. Utah 1999). Rather, a duty to disclose only exists if "the statement made is material, *and* the omitted fact is material to the statement in that it alters the meaning of the statement." *Anderson v. Spirit AeroSystems Holdings, Inc.*, 105 F. Supp. 3d 1246, 1260 (D. Kan. 2015) (emphasis added). Where, as here, Plaintiff fails to identify any statement rendered misleading by the purported omission, the omission is not actionable. *Id*. at 1260.

Take, for example, the Tenth Circuit's decision in *McDonald v. Kinder-Morgan, Inc.* Plaintiffs in that case contended that whenever the defendants disclosed the increased revenue and income resulting from its acquisition of a natural gas plant, they had a duty to further disclose financial risks associated with that plant. *McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 998 (10th Cir. 2002). The Tenth Circuit disagreed. It noted that a duty to disclose only arises when "the omitted fact is material to the statement in that it alters the meaning of the statement." *Id*. at 998. Because the omitted information about the plant's financial risks "[did] not alter the accuracy of the [revenue and income] information actually disclosed," the omission was immaterial to that statement. *Id*. at 998-99. As such, no duty to disclose existed.

Here, Defendants made *no* disclosures about the titration schemes used in Phase 3 or proposed in the NDA. Nor did Defendants predict the likelihood of NDA approval or indicate that Phase 3 results would likely lead to NDA approval. To the contrary, Defendants were entirely silent on these issues. Unable to point to any statement where Defendants discussed these issues, Plaintiff instead rests its claim on statements made about a different topic: Phase 3 results. *But neither the FDA, nor the Company, nor Plaintiff have ever questioned the accuracy of the disclosed statistics regarding the results of the Phase 3 clinical trial*. Plaintiff's blatant attempt to turn every statement about Phase 3 "results," Am. Compl. ¶ 21, into a statement about titration schemes and NDA approval is both inaccurate and inappropriate. Nor, more specifically, can Plaintiff turn every statement about dosage or titration *results*—including the percentage of patients who arrived at final dose after one titration, *see e.g.*, Am. Compl. ¶ 22—into a disclosure about the titration *scheme* used to achieve those results, *i.e.*, ***how*** the Company determines optimal dosage. *See* Am. Compl. ¶ 16 (defining dose titration as "the process" of determining optimal dosage). As in *McDonald*, the omitted facts about titration schemes and the likelihood of NDA approval "do[] not alter" the accuracy of Defendants' statements about Phase 3 results. Thus, even if an investor may have wanted to know this information, the Company was under no duty to disclose it.

In fact, silence—rather than disclosure—is the norm. The contents of unapproved NDAs contain closely guarded, highly confidential trade secrets, and regulations *explicitly* prohibit the FDA from disclosing them. *See* 21 CFR 314.430. As recognized by other courts, a drug manufacturer "has a competitive interest in seeing that the information contained in its NDA is not prematurely released to the public" because disclosure could allow competitors to use this highly sensitive information to create their own NDA "without incurring the time, labor, risk, and expense

involved in developing them independently." *Citizens Comm'n on Human Rights v. FDA, et al.*, No. 92CV5313, 1993 WL 1610471, *9 (C.D. Cal. May 10, 1993) (quoting Webb v. HHS, 696 F.2d 101, 103 (D.C. Cir. 1982). Further, "[i]nformation from unapproved supplements is considered particularly sensitive," because they "contain preliminary information on proposed strategies and tests," including "product dosage form[s]" that "contain a high percentage of trade secret, confidential, commercial and agency deliberative information that, as unapproved, does not currently have any impact on the public." *Id.* at *10. As such, drug manufacturers and the FDA "hold this information in extreme confidence," *id.*, and investors cannot have expected otherwise.

B. Plaintiff Has Not Pleaded A Misleading Statement With Particularity.

Finally, the Amended Complaint must also be dismissed because Plaintiff has not pleaded a misleading statement with particularity. Rather than identifying the specific statements rendered misleading by Defendants' alleged omissions, Plaintiff recites extensive public disclosures—some spanning numerous pages in length—and then summarily concludes that "[the] foregoing statements" are misleading. Am. Compl. ¶¶ 21, 23, 27, 29, 31, 33, 35, 37. This will not do. The PSLRA requires Plaintiff to, among other things, "*specify each statement* alleged to have been misleading." *Fleming*, 264 F.3d at 1258 (emphasis added). Further, underlying Plaintiff's entire claim is Plaintiff's unfounded *assumption* that the NDA would include the exact same dosing scheme used in Phase 3. Yet Plaintiff fails to identify any statement by Defendants remotely related to this point, let alone a statement designed to mislead investors regarding the titration scheme used in its NDA. For these reasons, the Amended Complaint must be dismissed for failure

to plead a misleading statement with particularity.[22] *See Anderson*, 105 F. Supp. 3d at 1261 (dismissing complaint because plaintiffs failed to tie the alleged omission to a material statement, and noting, "[w]ithout the benefit of guidance from the Plaintiffs, the Court is left to guess which statements related to production and costs trigger a duty to disclose contrary information").[23]

IV. PLAINTIFF HAS NOT PLEADED CONTROL PERSON LIABILITY

In order to state a claim for control person liability under Section 20(a), Plaintiff "must establish (1) a primary violation of the securities laws and (2) 'control' over the primary violator by the alleged controlling person." *Zagg*, 2014 WL 505152 at *8 (J., Benson) (quoting *Fleming*, 264 F.3d at 1270-71). Because Plaintiff has not sufficiently alleged a primary violation of §10(b), Plaintiff's § 20(a) claim fails as a matter of law. *Id*.

CONCLUSION

For the foregoing reasons, Plaintiff has not sufficiently pleaded a securities violation of Sections 10(b) or 20(a), and the Amended Complaint should be dismissed with prejudice.

[22] Included in the lengthy disclosures recited in the Amended Complaint are forward-looking statements and nonactionable puffery, neither of which can form the basis of a claim under § 10(b). *See, e.g.*, *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1119-1124 (10th Cir. 1997). To the extent Plaintiff is basing its claims on forward-looking statements or puffery, Defendants move to dismiss because they are inactionable, protected by the safe harbor and bespeaks caution doctrine, and because Plaintiff has failed to allege Defendants acted with actual knowledge. Am. Compl. ¶¶ 20, 22, 26, 28, 30, 32, 34, 36.

[23] Many of the alleged misstatements also occurred *before* the Company even filed its NDA, Am. Compl. ¶¶ 20, 22, 24, and Plaintiff does not explain how statements about Phase 3 results can be inconsistent with an NDA that had not yet even been finalized or filed.

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Respectfully submitted,

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